

**510(K) SUMMARY**

This summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of SMDA 1990 and 21 CFR §807.92.

The assigned 510(k) number is: K042226

**1. Submitter's Identification:**

Mr. Hao Jun Jie  
Syntex Healthcare Products Co., Ltd.  
No. 1 Fangjiazhuang Industrial Zone  
Xinji, Hebei Province  
P.R. China

Date Summary Prepared: July 01, 2004

**2. Name of the Device:**

Syntex Healthcare Products Co., Ltd.  
Syntex Powder-Free Nitrile Examination Glove, Tested for Chemotherapy

**3. Predicate Device Information:**

Syntex Healthcare Products Co., Ltd.  
Syntex Powder-Free Nitrile Examination Glove (K020493)

**4. Device Description:**

Classified by FDA's General and Plastic Surgery Device panel as Class I, 21 CFR 880.6250, Patient Examination Glove, 80LZA, and meets all requirements of ASTM Standard D6319-00a<sup>3</sup>.

**5. Intended Use:**

A patient examination glove is a disposable device intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between patient and examiner.

**6. Comparison to Predicate Devices:**

Syntex Healthcare Products Co., Ltd. Syntex Powder-Free Nitrile Examination Glove, Tested for Chemotherapy is substantially equivalent in safety and effectiveness to the Syntex Healthcare Products Co., Ltd. Syntex Powder-Free Nitrile Examination Glove.

**7. Discussion of Non-Clinical tests Performed for Determination of Substantial Equivalence are as follows:**

The standards used for Syntex Healthcare Products Co., Ltd. glove production are based on ASTM-D-6319-00a<sup>3</sup>. All testing meets requirements for Physical and Dimensions Testing conducted on gloves, Inspection Level S-2, AQL 4.0.

The FDA 1000 ml. Water Fill Test was also conducted with samplings of AQL 2.5, Inspection Level G-1, meeting these requirements. Primary Skin irritation and Skin Sensitization (allergic contact dermatitis) testing was conducted with results showing no primary skin irritant or sensitization reactions.

There are no special labeling claims and we do not claim our gloves as hypoallergenic on our labels.

A Residual Powder Test that based on ASTM D6124-01 for Starch at finished inspection is conducted to insure that our gloves meet our "powder-free" claims (contain no more than 2 mg powder per glove).

**8. Discussion of Clinical Tests Performed:**

Not Applicable – There is no hypoallergenic Claim.

**9. Conclusions:**

Syntex Healthcare Products Co., Ltd. Syntex Powder-Free Nitrile Examination Glove, Tested for Chemotherapy conform fully to ASTM-D-6319-00a<sup>3</sup> standard as well as applicable 21 CFR references, and, meets pinhole FDA requirements, biocompatibility requirements and labeling claims as shown by data in Section 7. There are no safety/efficacy issues or new claims from the "substantial equivalence" products cited.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

SEP 30 2004

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Syntex Healthcare Products Company Limited  
C/O Mr. James Chu  
Official Correspondent  
Gloveco, Incorporated  
590 West Central Avenue, #D  
Brea, California 92821

Re: K042226

Trade/Device Name: Syntex Powder-Free Nitrile Examination Glove, Tested for Use  
With Chemotherapy Drugs-Blue  
Regulation Number: 880.6250  
Regulation Name: Patient Examination Glove  
Regulatory Class: I  
Product Code: LZA  
Dated: August 13, 2004  
Received: August 17, 2004

Dear Mr. Chu:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,



Chiu Lin, Ph.D.

Director

Division of Anesthesiology, General Hospital,

Infection Control and Dental Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

Attachment A

INDICATIONS FOR USE

510(k) NUMBER (IF KNOWN): K 04 2226  
APPLICANT: Syntex Healthcare Products Co., Ltd.  
DEVICE NAME: Syntex Powder-Free Nitrile Examination Glove, Tested for USE with  
Chemotherapy DRUGS - BLUE

INDICATIONS FOR USE:

**A patient examination glove is disposable device intended for medical purpose that is worn on the examiner's hand or finger to prevent contamination between patient and examiner.**

Prescription Use \_\_\_\_\_  
(Per 21 CFR 801.109)

OR

Over-The-Counter-Use X \_\_\_\_\_  
(Optional Format 1-2-96)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED.)

Concurrent of CDRH, Office of Device Evaluation (ODE)

Rei Muley  
(Division Sign-Off)  
Division of Anesthesiology, General Hospital,  
Infection Control, Dental Devices

510(k) Number: K04 2226